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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,797	04/21/2004	Herbert M. Dean	dean0404con	5067

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,797	DEAN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed August 28, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 15, 16 and 21-23 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15, 16 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krumholz et al and Byrne et al. U.S. Patent No. 5,156,849 in view of Prisant et al.

Krumholz et al. teach that patients treated with aspirin (a platelet inhibitor) during hospitalization and patients prescribed beta blockers as a discharge medication were much more likely to be treated with aspirin at discharge (page 297, column 2) for secondary prevention after acute myocardial infarction. Further, in this study, the prescribed use of aspirin at discharge was correlated with several indicators of better overall health status. The prescribed use of aspirin at discharge was also associated with several specific patterns of care, including, *inter alia*, beta-blocker therapy at discharge (page 292 column 1 "Results"). Byrne et al. teach the combination of aspirin (a platelet inhibitor) and beta-blockers (β adrenergic blocking agents) in a single stable dosage unit. Regarding the method of encouraging of adherence to preventative medications following a heart attack, Prisant et al. teach that complex drug treatments can result in non-compliance and "fixed-dose" combination anti-hypertensive drugs can simplify dosing regimens, **improve compliance**, improve blood pressure control,

decrease dose-dependent adverse effects and reduce cost (page 283, column 1) and further teaches that beta blockers in reducing both stroke and heart failure–related events in patients with hypertension and in **preventing recurrent myocardial infarctions** in both high and low-risk patients with previous coronary episodes.

Regarding instant claim 21 drawn to the limitations above and further "providing instructions that indicate that the single dosage unit is for use by an individual who has had a heart attack", Regarding the kit, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package. *In re Gulack* is a legal decision which indicates that nonfunctional descriptive material in a claim does not distinguish the prior art in terms of patentability. It is noted that this is also discussed in the MPEP at section 2106, part VI. In the instant claims instructions that indicate the dosage unit is for once a day administration, is reasonably interpreted as such nonfunctional descriptive material which does not result in an actual physical action in the claimed methods. The instructions for use is information but not an action and thus this result of the instant claims does not result in a function but rather is a conceptual result only. Regarding claim 23, drawn to a post heart attack treatment adherence method comprising providing a plurality of single dosage units to the patient, Generally after discharge from a hospital after a cardiovascular event, a patient is presented with medications to take home and further with a prescription to fill at the local pharmacy wherein a plurality of dosage units are provided by the pharmacist. The single dosage unit formulation instantly claimed is disclosed in Byrne et al., supra.

It would have been made obvious to one of ordinary skill in art at the time it was made to employ a beta-adrenergic blocking agent with a platelet inhibitor in a single dosage unit to prevent secondary heart attacks motivated by the teaching of Krumholz et al. who disclose that the prescribed use of aspirin at discharge was correlated with several indicators of better overall health status and was also associated with beta blocker therapy at discharge (page 292 column 1 "Results"). To encompass both agents in a single dosage unit would have been obvious motivated by the teaching of Byrne et al. who disclose the combination of aspirin and beta adrenergic blocking agents in a single dosage unit. Further, motivation to encourage adherence to preventative medications following a heart attack comes from Prisant et al. who teach that "fixed-dose" combination agents improve compliance and prevent recurrent myocardial infarctions (page 287, column 3).

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Applicant states that Byrne teaches beta blockers as anti-hypertensive agents but contains no teaching or suggestion for secondary prevention of a heart attack. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. This motivation may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, filtered through the knowledge of one skilled in the art, Krumholz et al. teach that patients treated with aspirin (a platelet inhibitor) during hospitalization and patients prescribed beta blockers as a discharge medication were much more likely to be treated with aspirin at discharge (page 297, column 2) for **secondary prevention after acute myocardial infarction**. Further, regarding the single dosage unit to improve compliance, Byrne et al. teach combination of elements instantly claimed and Prisant teaches that fixed dose combination products improve compliance and prevent recurrent myocardial infarctions. With regard to table 2 of the Krumholz et al. study, pointing out the patients that did not receive aspirin at hospital discharge, the thrust of the teaching is drawn to the importance of discharging post MI patients with a beta blocker *and* aspirin. The reference does not teach away from the instant invention, it teaches it.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

April 1, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614